K093138

Caretalk®

File No: WMI-04-MT9000-FDA-05
Version: 1.2
Date: Feb.16, 2010

510(k) SUMMARY

FEB 12 2010

MT9000 Series Electro-Stimulator, K ( )

Submitter's Name: Shenzhen Dongdixin Technology Co., Ltd.

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Contact: Zhigang Zhao

Date Prepared: Sep.10,2009

1. Proposed Device:

A.

Trade Name:	MT9000 Combo TENS/EMS/IF/MIC Stimulator MT9002 EMS Stimulator
Classification Name:	Stimulator, Muscle, Powered
Regulation Number:	890.5850
Product Code:	IPF
Device Class:	II

B.

Trade Name:	MT9001 TENS Stimulator MT9004 MICROCURRENT Stimulator
Classification Name:	Stimulator, Nerve, Transcutaneous. For pain relief
Regulation Number:	882.5890
Product Code:	GZJ
Device Class:	II

C.

Trade Name:	MT9003 IF Stimulator
Classification Name:	Interferential current therapy
Regulation Number:	Unclassified
Product Code:	LIH
Device Class:	II

2. Predicate Device:

Legally Marketed Device: Sonicator Plus 940, ME940
Manufacturer: Mettler Electronics Corp
510(k) Number: K071137

3. Description of Proposed Device:

The MT9000 Series Stimulator, which includes models MT9000, MT9001, MT9002, MT9003, MT9004, are Transcutaneous Electrical Nerve Stimulator and muscle stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of units are controlled by the press buttons. Its intensity level is adjustable according to the needs of patients.

The five models MT9000, MT9001, MT9002, MT9003 and MT9004 have the same housing in a molded portable plastic case with a viewable LCD display, an accessible keypad, and accessible battery storage compartment. The case shape is rectangular.

The LCD is located on the upper half of the rectangular face of the device, above the keypad. The LCD is used to display system information to the user.

The device is equipped with a keypad composed of push buttons which are located below the LCD. The function for each button is defined by a symbol on the LCD corresponding to the button immediately below it. The process to set the parameter and attach lead wires to the five models is also the same. Yet, they have different liquid crystal display and parameters for patients to create their own settings.

The MT9000 Combo TEN/EMS/IF/MIC Stimulator is the combination unit with the TENS, EMS, IF and MICROCURRENT functions, the function can be selected by press buttons. The range of settings is identical to those of MT9001, MT9002, MT9003 and MT9004. The difference on the five units can be identified by the LCD display.

4. Proposed Device Intended Use Statement:

Device Name:

MT9000 Combo Stimulator, MT9001 TENS Stimulator, MT9002 EMS Stimulator,

MT9003 IF Stimulator, MT9000 MICROCURRENT Stimulator

Indications for Use:

MT9000 Combo TENS/EMS/IF/MIC Stimulator

For TENS mode

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

For EMS mode

1. Relaxation of muscle spasm
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

For IF mode

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

For MIC mode

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

MT9001 TENS Stimulator

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

MT9002 EMS Stimulator

1. Relaxation of muscle spasm
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

MT9003 IF Stimulator

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

MT9004 MICROCURRENT Stimulator

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

5. Biocompatibility Certification:

Electrodes to be provided with this device are from the manufacturer Top-Rank Health Care Equipment Co., Ltd (K070612) who submitted in 2007.

The shell of device is used ABS material; this material has passed Biocompatibility

testing in Jiangsu TUV Product Service Ltd. Shanghai Branch. Identification No: 080960.

6. **Technological Characteristics and Substantial Equivalence**

Both the MT9000 Series Electro-Stimulator and the Sonicator Plus 940, ME940 Stimulator have the same intended use, fundamental technology, and operation characteristics. A side-by-side comparison of the MT9000 Series Electro-Stimulator and the cited predicate devices is included in the 510(k). The MT9000 Series Electro-Stimulator is substantially equivalent to the technologies provided by the predicate devices.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The MT9000 Series Electro-Stimulator did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Nonclinical testing was performed in order to validate the design according with the company's specified design requirements, and to assure conformance with the following voluntary design standards:

- IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for safety".
- IEC 60601-1-2 "Medical electrical equipment - Part 1-2: General requirements for safety – Collateral Standard"
- IEC 60601-2-10 "Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators"

8. **Conclusions:**

The MT9000 Series Stimulator, which includes models MT9000, MT9001, MT9002, MT9003 and MT9004, has the same intended use and technological characteristics as the predicate device of Sonicator Plus 940, Model ME940 device. Moreover, bench testing, safety report and Risk Analysis Report documentation supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, the MT9000 Series Electro-Stimulator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Xilixiaobaimang Nanshan District
Shenzhen, CN-44, Guangdong Province
People's Republic of China 518108

FEB 12 2010

Re: K093138
Trade/Device Name: MT9000 Combo TENS/EMS/IF/MIC Stimulator, MT 9001 TENS Stimulator, MT9002 EMS Stimulator, MT9003 IF Stimulator, MT9004 Microcurrent Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, GZJ, LIH
Dated: February 2, 2010
Received: February 2, 2010

Dear Mr. Zhao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

ACTING DSORD DIRECTOR

FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Caretalk®

File No: WMI-04-MT9000-FDA-04
Version: 1.2
Date: Feb.16, 2010

Indications for Use

510(k) Number ( ):

Device Name:

MT9000 Combo TENS/EMS/IF/MIC Stimulator, MT9001 TENS Stimulator, MT9002 EMS Stimulator, MT9003 IF Stimulator, MT9004 MICROCURRENT Stimulator

Indications for Use:

MT9000 Combo TENS/EMS/IF/MIC Stimulator

For TENS mode

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

For EMS mode

1. Relaxation of muscle spasm
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

For IF mode

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

For MIC mode

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

MT9001 TENS Stimulator

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093138

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File No: WMI-04-MT9000-FDA-04
Version: 1.2
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MT9002 EMS Stimulator

1. Relaxation of muscle spasm
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

MT9003 IF Stimulator

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

MT9004 MICROCURRENT Stimulator

1. Symptomatic relief of chronic intractable pain,
2. Post traumatic pain
3. Post surgical pain

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M.MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093138